

Remarks

Claims 1, 3, 6-9, 12, 15, 18, 19, 43, 45-50, 52, 53, 58, 60, 62, 64, 66, and 71-75 were pending in the subject application. By this Amendment, new claims 76 and 77 have been added. Support for the new claims can be found throughout the subject specification, including, for example, at page 12, lines 20-28, and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1, 3, 6-9, 12, 15, 18, 19, 43, 45-50, 52, 53, 58, 60, 62, 64, 66, and 71-77 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the some of the rejections under 35 USC §112, first paragraph, and the rejection under 35 USC §103(a). Applicants also gratefully acknowledge the Examiner's indication that claims 43, 45-50, 52, 64, 71, and 72 appear to be allowable in the subject application. The Examiner also indicates that claims 1, 3, 6-9, 12, 15, 18, 19, 60, 66, and 74 will also be allowable if claim 1 is amended as discussed below.

Claim 1 is objected to due to a typographical error. Applicants gratefully acknowledge the Examiner's careful review of the claims. In accordance with the Examiner's suggestion, Applicants have deleted one of the recitations of "production" in claim 1. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 53, 58, 62, and 73 remain rejected under 35 USC §112, first paragraph, as non-enabled by the subject specification. The Examiner asserts that the specification does not enable administration of nucleic acid or plasmid via an oral or mucosal route. Applicants respectfully assert that the subject specification does enable the claimed invention. It is well accepted in the art that nucleic acid and plasmids can be administered via an oral or mucosal route and be effective. Attached with this Amendment is a copy of a publication by Roy *et al.* (1999), which is but one example of administration of nucleic acid-chitosan nanoparticles via an oral route. Nucleic acid-chitosan nanoparticles also provide for efficient delivery via a mucosal route. Thus, Applicants have submitted evidence of oral and mucosal administration of nucleic acid in contrast to the Kai and Ochiya reference cited by the Examiner. A person of ordinary skill in the art, having the benefit of the teachings of the subject specification, would expect that nucleic acid or plasmid can be

administered via an oral or mucosal route in the claimed methods. Thus, Applicants respectfully assert that the subject specification does enable administration of nucleic acid and plasmid via oral and mucosal routes. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Doran R. Pace
Patent Attorney
Registration No. 38,261
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: Saliwanchik, Lloyd & Saliwanchik
A Professional Association
P.O. Box 142950
Gainesville, FL 32614-2950

DRP/mv

Attachment: Roy *et al.* (1999)